

### **REMARKS**

This responds to the Office Action mailed on March 14, 2008.

Claims 1, 3, 8, 11, 13, and 18 are amended, and claims 7 and 17 are canceled. Claims 1, 3-6, 8-11, 13-16, and 18-20 are now pending in this application.

#### **§102 and §103 Rejection of the Claims**

Claims 1, 4-8, 11 and 14-18 were rejected under 35 U.S.C. § 102(e) for anticipation by Hill et al. (U.S. Patent No. 5,718,208). Claims 1, 3-11 and 13-20 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Adams et al. (U.S. Publication 2003/0229380) in view of Gross et al. (U.S. Publication 2003/0045909). Claims 3, 9, 10, 13, 19 and 20 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Hill et. al. The rejections are traversed and reconsideration is respectfully requested.

Regarding the anticipation rejections of claims 1, 4, 11, and 14 based upon the Hill et al. reference, the Office Action states that:

Regarding claims 1, 4, 11 and 14, Hill'208 discloses an implantable device for delivering cardiac function therapy (abstract) comprising a plurality of pacing channels for delivering pacing pulses to multiple ventricular sites (abstract; column 6, lines 26-47); a parasympathetic stimulation channel for stimulating parasympathetic nerves (column 5, line 55 through column 6, line 19; column 7, line 62 through column 8, line 17); a sensor for measuring cardiac output (column 4, lines 35-44); a controller for controlling the delivery of pacing pulses to multiple ventricular sites (Fig. 1, controller 30; abstract; column 6, lines 26-47); wherein the controller delivers the ventricular pacing to prevent the heart rate slowing below a specified minimum value (abstract); wherein it is taken that the controller modulates delivery of parasympathetic stimulation in accordance with the cardiac output measurement (column 6, lines 9-19).

Applicant has examined the abstract and col. 6, lines 26-47 of Hill et al. and finds no reference to multi-site ventricular pacing as asserted by the Office Action. Applicant has examined col. 4, lines 35-44 of Hill et al. and finds no description of a sensor for measuring cardiac output. The only thing relating to cardiac output is the following sentence as col. 4, lines 39-41: "Alternatively, the heart may be paced with an electrical pacing system, thereby maintaining a

normal cardiac output.” Applicant has examined col. 6, lines 9-19 of Hill et al. and finds only a description of ceasing delivery of parasympathetic stimulation if the heart has been stopped for too long. Measurement of cardiac output refers to the measurement of the blood pumped by the heart and not to mere detection of whether the heart is stopped or not. Applicant thus finds no description of modulating the delivery of parasympathetic stimulation in accordance with measured cardiac output. Reconsideration and withdrawal of the anticipation rejections is respectfully requested.

Regarding the anticipation rejections of claims 5, 7, 8, 15, 17 and 18 based upon Hill et. al, the Office Action states that the reference “discloses delivery of parasympathetic stimulation in response to a heart rate condition sensed by electrodes 210 and 220 in Fig. 2, wherein it is contemplated that heart rate is an indicator of a patient's exertion level.” The Office Action goes on to state that “Hill '208 discloses delivering nerve and pacing stimulation to return the heart to a normal cardiac output, or maintain a normal cardiac output (column 4, lines 32-44), wherein a normal cardiac output is considered to be indicative of the adequacy of the cardiac output.” Applicant does not believe any of the cited portions of Hill et. al constitute a teaching or suggestion for modulating the delivery of parasympathetic stimulation in accordance with a parameter computed from the measured exertion level and measured cardiac output that indicates the adequacy of the cardiac output as recited by independent claims 1 and 11 as amended herein and as previously cited by cancelled claims 7 and 17. Firstly, as stated above, Applicant finds no reference to measurement of cardiac output in Hill et. al where cardiac output is defined as the blood pumped by the heart. Secondly, as best understood, the Office Action is contending that the measurement of heart rate of heart rate is equivalent to the claimed measurement of exertion level. Heart rate is indeed related to exertion level in the normal chronotropically competent individual. It is not related to exertion level, however, when the intrinsic heart rate is either slowed by parasympathetic stimulation or prevented from slowing by artificial pacing, the measured heart rate in the latter case being only the programmed pacing rate and not related to the subject's exertion level. Furthermore, if the Office Action is arguing that measurement of heart rate as taught by Hill et. al constitutes both measurement of cardiac output and measurement of exertion level, there is still no disclosure of computing a parameter from the measured exertion level and measured cardiac output that indicates the adequacy of the cardiac

output and modulating the delivery of parasympathetic stimulation in accordance therewith. Applicant thus believes that the pending claims are neither anticipated nor rendered obvious by Hill et. al.

As best understood, the Office Action alleges that Adams et. al and/or Gross et. al disclose the delivery of multi-site ventricular pacing in conjunction with parasympathetic stimulation and controlling the parasympathetic stimulation in accordance with cardiac output. Applicant does not believe that either Adams et. al or Gross et. al teach or suggest modulating the delivery of parasympathetic stimulation in accordance with a parameter computed from the measured exertion level and measured cardiac output that indicates the adequacy of the cardiac output as recited by independent claims 1 and 11 as amended herein and as previously cited by cancelled claims 7 and 17. In rejecting claims 5, 7, 8, 15, 17 and 18, the Office Action states that Adams et. al “discloses monitoring a patient's blood pressure, and the use of an activity sensor for monitoring a patient's exertion level (see for example paragraphs 46, 55 and 64). It is taken that the parameter computed from exertion level and cardiac output is indicative of the adequacy of the cardiac output (paragraphs [9], [63], [98], [193], [215]).” Simply measuring exertion level and cardiac output, however, does not constitute computing a parameter from the measured exertion level and cardiac output indicative of the adequacy of the cardiac output. A particular cardiac output adequate for a particular exertion level may be inadequate for a higher exertion level. Applicant finds no teaching or suggestion in any of the cited references for determining the adequacy of cardiac output by any means. Necessarily, Applicant also finds no teaching or suggestion for modulating the delivery of parasympathetic stimulation in accordance a parameter related to the adequacy of measured cardiac output. Applicant thus believes that the pending claims as amended are not rendered obvious by Adams et. al and Gross et. al. Reconsideration and withdrawal of the rejections is respectfully requested.

**CONCLUSION**

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (847) 432-7302 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

SCHWEGMAN, LUNDBERG & WOESSNER, P.A.  
P.O. Box 2938  
Minneapolis, MN 55402  
(847) 432-7302

Date June 16, 2008

By J. Kevin Parker  
J. Kevin Parker  
Reg. No. 33,024

**CERTIFICATE UNDER 37 CFR 1.8:** The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 16th day of June 2008.

Kate Gannon

Name

Kate Gannon  
Signature